

Exhibit A

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KELLY MILLER

: PHILADELPHIA COUNTY
: COURT OF COMMON PLEAS
: TRIAL DIVISION

: September Term, 2023
: No. _____

: DEMAND FOR A JURY TRIAL

Case ID: 230901944

NOTICE TO DEFEND

NOTICE You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

PHILADELPHIA COUNTY BAR ASSOCIATION
LAWYER REFERRAL AND
INFORMATION SERVICE
ONE READING CENTER
PHILADELPHIA, PENNSYLVANIA 19107
TELEPHONE: (215) 238-6333
TTY (215) 451-6197

AVISO Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) dias de plazo al partir de la fecha de lan demanda y la notificacion. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademias, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted. LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIOI, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

**ASOCIACION DE LICENCIADOS
DE FILADELFIA**
SERVICIO DE REFERENCIA E
INFORMACION LEGAL
ONE READING CENTER
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PARTIES

1. Plaintiff, Kelly Miller, is a citizen of the United States, and is a resident of the State of Pennsylvania.

2. Defendant, NOVO NORDISK INC. (“Novo Nordisk”), is a Delaware corporation, which has its principal place of business at 800 Scudders Mill Road, Plainsboro, NJ 08536. Novo Nordisk has conducted business and derived substantial revenue from within the State of Pennsylvania.

3. Defendant Novo Nordisk Inc. is wholly owned by Defendant Novo Nordisk US Commercial Holdings, Inc.

4. Defendant Novo Nordisk US Commercial Holdings Inc. is a Delaware corporation with a principal place of business at 103 Foulk Road, Wilmington, Delaware.

5. Defendant Novo Nordisk US Commercial Holdings Inc. is wholly owned by Defendant Novo Nordisk US Holdings Inc.

6. Defendant Novo Nordisk US Holdings Inc. is a Delaware corporation with a principal place of business at 103 Foulk Road, Wilmington, Delaware.

7. Defendant Novo Nordisk US Holdings Inc. is wholly owned by Defendant Novo Nordisk A/S.

8. Defendant Novo Nordisk A/S is a public limited liability company organized under the laws of Denmark with a principal place of business in Bagsværd, Denmark.

9. Defendant Novo Nordisk A/S and its subsidiaries and affiliates named herein are collectively referenced as “the Novo Nordisk Defendants” and “Novo Nordisk.”

10. Defendant Novo Nordisk North America Operations A/S is a company organized under the laws of Denmark with a principal place of business in Bagsværd, Denmark.

11. Novo Nordisk Research Center Seattle, Inc. is a Delaware corporation with a principal place of business at 530 Fairview Ave. N., Seattle, Washington.

12. Novo Nordisk Pharmaceutical Industries LP is a Delaware corporation with a principal place of business at 3611 -3612 Powhatan Road, Clayton, North Carolina.

13. The Novo Nordisk Defendants' website states that "the vast majority of our U.S. injectable diabetes and obesity products are produced and packaged at the Clayton aseptic fill-finish site."¹ Upon information and belief, this refers to Novo Nordisk's manufacturing facility in Clayton, North Carolina, operated by Novo Nordisk Pharmaceutical Industries LP.

14. Upon information and belief, Defendant Novo Nordisk Pharmaceutical Industries LP is the labeler for Ozempic and Wegovy, and Defendants Novo Nordisk A/S and Novo Nordisk Inc. are identified on Ozempic and Wegovy's label.² The Novo Nordisk Defendants also designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed Ozempic and Wegovy.

15. Upon information and belief, Defendants failed to warn the end users of Ozempic and Wegovy of the complications and devastating effects the drug which the company knew or should have known.

16. Upon information and belief, Defendants' marketing was deceptive and misleading about the real risks associated with use of Ozempic and Wegovy of which the company knew or should have known.

¹ <https://www.novonordisk-us.com/about/who-we-are/north-carolina.html> (last visited on September 17, 2023).

² <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=adec4fd2-6858-4c99-91d4-531f5f2a2d79> (last visited on September 17, 2023).

JURISDICTION AND VENUE

17. This Court has personal jurisdiction, pursuant to 42 Pa.C.S. §5301 et seq., over the Defendants because, at all relevant times, they have engaged in continuous and substantial business activities in the Commonwealth of Pennsylvania.

18. Courts of Common Pleas have statewide jurisdiction in Pennsylvania.³

19. Plaintiff is a resident of the State of Pennsylvania.

20. Thus, jurisdiction is proper in Philadelphia.

21. This Court has personal jurisdiction over the Defendants consistent with the United States Constitution and 42 Pa. Consol. Stat. Ann. §5322 (Pennsylvania's "long arm" statute), as Plaintiff's claims arise out of Defendants' transaction of business and the tortious acts within the State of Pennsylvania, and by virtue of Defendants' substantial, continuous, and systematic contacts with the State of Pennsylvania.

22. Defendants routinely market, conduct business, and are domiciled in Pennsylvania, where Plaintiff is a resident and where her injury occurred, as such jurisdiction is proper.

23. Venue is further proper in this Court pursuant to Pa. R. Civ. P. 1006 and 2179, where Plaintiff's causes of action arose, and/or where a transaction or occurrence took place out of which this cause of action arose.

³ Per § 2:177. Courts of common pleas, generally, 1 Standard Pennsylvania Practice 2d § 2:177

BACKGROUND

I. An Accidental Blockbuster: The Development of Ozempic and Wegovy

24. It began at Novo Nordisk when researchers discovered that Liraglutide, a GLP-1 drug, manufactured by the company, when injected in rats, caused the animals to nearly stop eating.⁴

25. GLP-1 agonists are a class of medications that can help lower blood sugar levels and promote weight loss.⁵ GLP-1 agonist medications work by mimicking a naturally occurring GLP-1 hormone. In medication terms, an agonist is a manufactured substance that attaches to a cell receptor and causes the same action as the naturally occurring substance.⁶

26. In other words, GLP-1 medications bind to GLP receptors to trigger the effects (or roles) of the GLP-1 hormone. The higher the dose of the GLP-1 agonist, the more extreme the effects.⁷

27. “These rats, they starved themselves,” Dr. Knudsen said in a video series released by the Novo Nordisk Foundation, “so we kind of knew there was something in some of these peptides that was really important for appetite regulation.”⁸

28. Human subjects who got an intravenous drip of GLP-1 ate 12% less at a lunch buffet than those who got a placebo.⁹

29. Novo Nordisk decided to begin studying Liraglutide as both a diabetes drug and an obesity drug.¹⁰

⁴ <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html> (last visited September 17, 2023)

⁵ <https://my.clevelandclinic.org/health/articles/13901-glp-1-agonists> (last visited September 17, 2023)

⁶ *Id.*

⁷ *Id.*

⁸ <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html> (last visited September 17, 2023).

⁹ *Id.*

¹⁰ *Id.*

30. In 2010, Liraglutide was approved for diabetes. Novo Nordisk named it Victoza.¹¹

31. After Liraglutide was approved for diabetes, a proposal to study the drug for weight loss moved forward.¹²

32. After clinical trials, The FDA approved another formulation of a GLP-1, Saxenda for obesity in 2014.¹³

33. Saxenda's effects on weight loss, however, were modest. Patients lost about 5% of their weight.¹⁴

34. Saxenda also required daily injections.¹⁵

35. In an effort to find ways to make a longer-lasting GLP-1 so patients would not have to inject themselves every day, a different GLP-1 drug, Semaglutide (Ozempic) was created.¹⁶

36. Ozempic is also known as semaglutide. One way in which Ozempic works is by stimulating insulin production and reducing glucose production in the liver helping to lower blood sugar levels.

37. On December 5, 2016, the Novo Nordisk Defendants announced submission of a new drug application (NDA) to the FDA for regulatory approval of once-weekly injectable semaglutide, a new glucagon-like peptide-1 (GLP-1) medication for treatment of type 2 diabetes. In the announcement, Defendants represented that in clinical trials "once-weekly" semaglutide had a safe and well tolerated profile with the most common adverse event being nausea."¹⁷

¹¹[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2957743/#:~:text=The%20incretin%20mimetic%20liraglutide%20\(Victoza,adults%20with%20type%2D2%20diabetes.&text=Liraglutide%20is%20also%20approved%20in%20Europe%20and%20Japan](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2957743/#:~:text=The%20incretin%20mimetic%20liraglutide%20(Victoza,adults%20with%20type%2D2%20diabetes.&text=Liraglutide%20is%20also%20approved%20in%20Europe%20and%20Japan) (last visited September 18, 2023).

¹² <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html> (last visited September 17, 2023).

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ <https://ml.globenewswire.com/Resource/Download/d2f719e1-d69f-4918-ae7e-48fc6b731183> (last visited on September 17, 2023).

38. The NDA Novo Nordisk Inc. (NDA 209637), requested that the FDA grant it approval to market and sell Ozempic (semaglutide) 0.5 mg or 1 mg injection in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

39. On December 5, 2017, the FDA approved the application and granted premarket approval as NDA 209637.¹⁸

40. In addition to diabetic control, Ozempic also caused 15% weight loss, which was three times the loss caused by its predecessor Saxenda.¹⁹

41. There was no obvious reason for this increase in weight loss percentage.²⁰

42. In 2018, a year after Ozempic's approval for diabetes, the company started a clinical trial in patients who were overweight or suffered from obesity.²¹

43. The results of the trial demonstrated that participants who were overweight or obese, 2.4 mg of semaglutide once weekly **plus** lifestyle intervention was associated with sustained, clinically relevant reduction in body weight.²²

44. The trial data also pointed out that more participants in the semaglutide group than in the placebo group discontinued treatment owing to gastrointestinal events (59 [4.5%] vs. 5 [0.8%]).

45. In 2018, a year after Ozempic's approval for diabetes, Defendants started a clinical trial to study its effects on weight loss.²³

¹⁸ https://www.accessdata.fda.gov/Ozempicatfda_docs/appletter/2017/209637s000ltr.pdf (last visited on September 17, 2023).

¹⁹ <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html> (last visited September 17, 2023).

²⁰ *Id.*

²¹ *Id.*

²² <https://www.nejm.org/doi/full/10.1056/NEJMoa2032183> (last visited September 17, 2023)

²³ <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html> (last accessed September 17, 2023)

46. On March 20, 2019, Defendant Novo Nordisk Inc. submitted supplemental new drug application (sNDA) 209637/S-003 for Ozempic (semaglutide) 0.5 mg or 1 mg injection, requesting approval to expand its marketing of Ozempic by adding an indication to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease.²⁴ On January 16, 2020, the FDA approved sNDA 209637/S-003.²⁵

47. On May 28, 2021, Defendant Novo Nordisk Inc. submitted sNDA 209637/S-009, requesting approval for a higher 2 mg dose of Ozempic (semaglutide) injection. On March 28, 2022, the FDA approved sNDA 209637/S-009.²⁶

48. On March 28, 2022, the Novo Nordisk Defendants announced the FDA's approval of sNDA 209637/S-009 for a higher 2 mg dose of Ozempic (semaglutide) injection. In the press release, Defendants represented Ozempic as having "proven safety and efficacy" and they continued to advertise that "it can help many patients lose some weight."²⁷ As with its prior press releases, Defendants disclosed Important Safety Information and a provided link to the Medication Guide and Prescribing Information, but severe gastrointestinal events including gastroparesis and gastroenteritis were not identified as risks.

49. By March of 2021, Defendants had completed the clinical trial studying semaglutide for weight loss. Its results were published March 18, 2021.²⁸

²⁴ <https://www.prnewswire.com/news-releases/novo-nordisk-files-for-us-fda-approval-of-oral-semaglutide-for-blood-sugar-control-and-cardiovascular-risk-reduction-in-adults-with-type-2-diabetes-300815668.html> (last visited on September 17, 2023).

²⁵ https://www.accessdata.fda.gov/Ozempicatfda_docs/applletter/2020/209637Orig1s003ltr.pdf (last visited on September 17, 2023).

²⁶ https://www.accessdata.fda.gov/Ozempicatfda_docs/applletter/2022/209637Orig1s009ltr.pdf (last visited on September 17, 2023).

²⁷ <https://www.prnewswire.com/news-releases/novo-nordisk-receives-fda-approval-of-higher-dose-ozempic-2-mg-providing-increased-glycemic-control-for-adults-with-type-2-diabetes-301512209.html> (last visited on September 17, 2023).

²⁸ <https://www.nejm.org/doi/full/10.1056/NEJMoa2032183> (last visited September 17, 2023)

50. In addition to the results, the published study – which was funded by Defendants – argued that “Obesity is a chronic disease and global public health challenge.”²⁹

51. On June 4, 2021, the FDA announced that Wegovy was approved for weight loss.³⁰

52. This was the first FDA approved drug for weight loss since 2014.³¹

53. Wegovy was initially approved for adults with obesity (BMI over 30) or overweight (BMI over 27) and at least one chronic health condition.³²

54. On December 23, 2022, Novo Nordisk announced FDA approval of Wegovy injection – along with reduced calorie meal plan and exercise – for the treatment of obesity in adolescents aged 12 years and older.³³

55. Novo Nordisk, and its competitor Eli Lilly, currently have at least twelve more obesity medications in development.³⁴

56. Novo Nordisk recently announced the \$1 Billion dollar acquisition of a Canadian pharmaceutical company developing obesity and diabetes treatments.³⁵

57. Novo Nordisk has stated that “[t]he acquisition of Inversago Pharma will further strengthen our clinical development pipeline in obesity and related disorders.”³⁶

²⁹ *Id.*

³⁰ <https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treatment-chronic-weight-management-first-2014> (last accessed September 17, 2023)

³¹ *Id.*

³² *Id.*

³³ <https://www.novonordisk-us.com/media/news-archive/news-details.html?id=151389> (last visited September 17, 2023).

³⁴ <https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin> (last accessed September 17, 2023)

³⁵ <https://thehill.com/business/4147983-ozempic-maker-novo-nordisk-to-acquire-obesity-drug-developer-in-1b-deal/> (last visited on September 17, 2023).

³⁶ *Id.*

II. Defendants Create a Market: Millions Spent on Marketing and Promotion Create a Media Frenzy and Mega Seller

58. Defendants have been working for years to change the medical consensus as it relates to obesity. Conventionally, evidence-based approaches to obesity focused on lifestyle: eating whole, nutrition foods, exercising, reducing stress, and obtaining adequate sleep. In contrast, Defendants have spent millions of dollars have been spent marketing the belief that sustained weight loss is only achievable by using Defendant’s medications at a cost of more than \$1000 a month. Their marketing has worked – over 135,000 new prescriptions are being written each week just for Wegovy.³⁷ Throughout their marketing, Defendants fail to disclose all the potential side effects – including those that can lead to hospitalization and death.

59. On February 5, 2018, the Novo Nordisk Defendants announced that they had started selling Ozempic in the United States and touted the medication as a “new treatment option[]” that “addresses the concerns and needs of people with diabetes[.]” The Novo Nordisk Defendants offered an “Instant Savings Card to reduce co-pays to as low as \$25 per prescription fill for up to two years.”

60. Novo Nordisk was not permitted to market Ozempic for weight loss without F.D.A. approval for that specific indication.³⁸

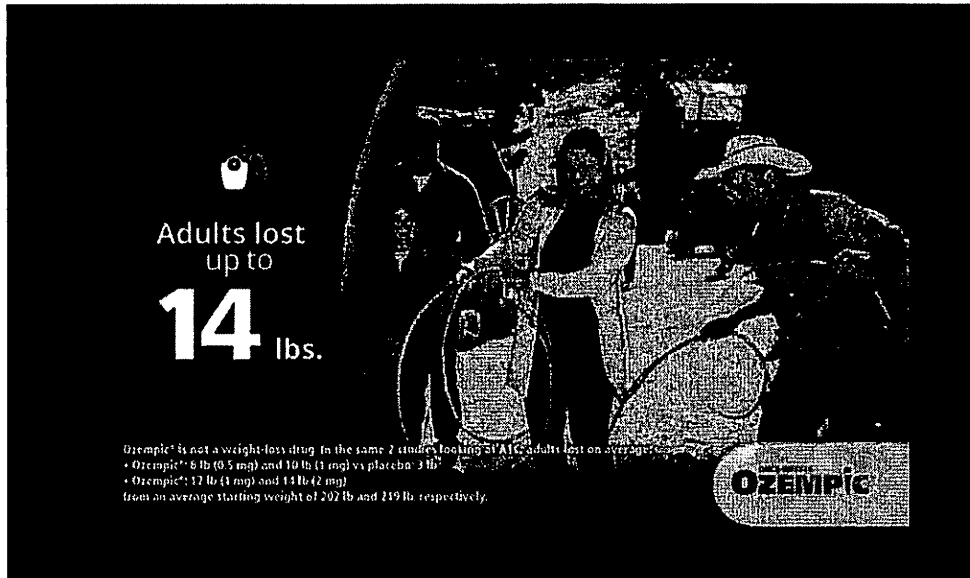
61. Despite the lack of FDA approval, and before Wegovy ever received separate approval, Novo Nordisk had already begun mentioning weight loss in their Ozempic commercials.³⁹

³⁷ <https://www.reuters.com/business/healthcare-pharmaceuticals/obesity-drug-wegovys-popularity-has-us-employers-rethinking-insurance-coverage-2023-06-27/> (last visited September 17, 2023).

³⁸ <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html> (last visited September 18, 2023).

³⁹ *Id.*

62. On July 30, 2018, the Novo Nordisk Defendants launched their first television ad for Ozempic to the tune of the 1970s hit pop song “Magic” by Pilot wherein the Novo Nordisk Defendants advertised that “adults lost on average up to 12 pounds” when taking Ozempic.⁴⁰



63. Over the next five years, the Novo Nordisk Defendants spent \$884,000,000 on running television ads in the United States to promote its semaglutide Ozempic, Wegovy and Rybelsus with the majority of the spending allocated specifically to advertising Ozempic.⁴¹

64. By 2021 Defendant’s aggressive marketing of the weight loss benefits of Ozempic, sophisticated use of social media, and America’s socially ingrained desire to be thin had reached a tipping point.⁴²

65. Over 4,000 marketing advertisements for Ozempic and similar weight-loss medications have been placed on Facebook and Instagram.⁴³

⁴⁰ <https://www.ispot.tv/ad/d6Xz/ozempic-oh> (last visited September 18, 2023).

⁴¹ https://medwatch.com/News/Pharma_Biotech/article15680727.ece (last visited on September 18, 2023).

⁴² <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html> (last visited on September 18, 2023).

⁴³ <https://www.nbcnews.com/tech/internet/ozempic-weight-loss-drug-ads-instagram-wegovy-semaglutide-rcna88602> (last visited on September 18, 2023).

66. According to open payments data, Novo Nordisk spent \$33,927,336.42 on marketing/consulting/travel/food and beverage/etc. to physicians in 2022 alone.⁴⁴

67. Adults are not the only ones targeted through marketing and media promotion, teenagers are too.

68. The problem is, Ozempic is not approved for teenagers.

69. Wegovy only recently received approval by the FDA in December as a treatment for teenagers with obesity in limited circumstances.⁴⁵

70. That hasn't stopped teens from being a target through various mediums like Tik Tok.

71. On TikTok, the hashtag #Ozempic had 273 million views as of November 22, 2022,⁴⁶ and currently has over 1.2 billion views.⁴⁷

72. The hashtag #wegovyweightloss has 163.2 million views as of September 9, 2023, on TikTok.

73. The hashtag #ozempicjourney has 199.5 Million views, as of September 9, 2023, on TikTok.

74. Novo Nordisk partnered directly with Meta and Instagram to run marketing campaigns. One diabetes marketing campaign achieved a dramatic 28% direct engagement rate with their polls.⁴⁸ This was a lauded result presented in a case study by Meta.

75. The marketing is working, and teenagers are using Wegovy.⁴⁹

76. The long-term safety of Wegovy when used in perpetuity in teenagers is

⁴⁴ <https://openpaymentsdata.cms.gov/company/100000000144> (last visited on September 18, 2023).

⁴⁵ [Ozempic in Teens Is a Mess - The Atlantic](#) (last visited on September 18, 2023).

⁴⁶ <https://www.nytimes.com/2022/11/22/well/ozempic-diabetes-weight-loss.html> (last visited on September 18, 2023).

⁴⁷ <https://www.tiktok.com/tag/ozempic> (last visited on August 1, 2023).

⁴⁸ <https://business.instagram.com/success/novo-nordisk> (last visited September 17, 2023).

⁴⁹ <https://time.com/6285055/wegovy-teenagers-weight-loss-risks/> (last visited September 17, 2023).

unknown.⁵⁰

77. If teenagers – or any patient – should stop taking Ozempic or Wegovy, studies show they immediately gain the weight back.⁵¹

78. On July 10, 2023, a global media company declared Ozempic as “2023’s buzziest drug” and one of the “Hottest Brands, disrupting U.S. culture and industry.”⁵²

79. Novo Nordisk reportedly spent about a hundred million dollars advertising Ozempic last year.⁵³

80. Jimmy Kimmel joked about Ozempic at the Oscars.⁵⁴

81. Howard Stern has joked and discussed Ozempic.⁵⁵ Interestingly, Stern notes that the “catchy” theme song “distracts” the listener from actually hearing any of the listed side effects.⁵⁶

82. Both Elon Musk and Chelsea Handler are among the celebrities who have admitted to using the drug for weight loss.⁵⁷

83. Novo Nordisk has partnered directly with other celebrities as paid spokespersons, including Queen Latifah.⁵⁸

84. As part of overall campaigns to target Black, Brown, and Hispanic consumers with their marketing campaigns and social media partnerships with influencers. In addition to Queen

⁵⁰ <https://time.com/6285055/wegovy-teenagers-weight-loss-risks/> (last visited September 17, 2023).

⁵¹ <https://www.healthline.com/health-news/weight-regain-after-stopping-ozempic> (last visited September 17, 2023).

⁵² <https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brands-most-popular-marketing-2023/2500571> (last visited on September 17, 2023).

⁵³ <https://www.npr.org/sections/health-shots/2023/08/07/1192279278/ozempic-and-wegovy-maker-courts-prominent-black-leaders-to-get-medicare-favor> (last visited September 17, 2023).

⁵⁴ <https://www.usatoday.com/story/life/health-wellness/2023/03/13/ozempic-sweeping-hollywood-celebrities-weight-loss/11428801002/> (last accessed September 17, 2023).

⁵⁵ <https://www.youtube.com/watch?v=QD-nCQn1Ads> (last visited on September 17, 2023).

⁵⁶ *Id.*

⁵⁷ <https://www.insider.com/ozempic-celebrities-denied-semaglutide-wegovy-weight-loss-drugs-khloe-kardashian-2023-3#chelsea-handler-said-she-was-on-semaglutide-without-realizing-it-7> (last visited on September 18, 2023).

⁵⁸ <https://www.npr.org/sections/health-shots/2023/08/07/1192279278/ozempic-and-wegovy-maker-courts-prominent-black-leaders-to-get-medicare-favor> (last visited September 17, 2023)

Latifah, Novo Nordisk has paid Yvette Nicole Brown to serve as a paid spokesperson.⁵⁹

85. In 2021, Novo Nordisk even gave between \$100,000 and \$399,999 to the Congressional Black Caucus Foundation.⁶⁰

86. Novo Nordisk (combined with Eli Lilly) are spending roughly ten million dollars annually on lobbying.⁶¹

87. A primary focus of that lobbying is the proposed Treat and Reduce Obesity Act, which has been introduced in congressional sessions annually since 2012, and which would require Medicare to cover, among other treatments, chronic-weight-management drugs.⁶²

88. Defendants – and their competitors – have promoted the message that “obesity is a disease” and largely due to “genetics” and “not a choice” and that coverage of pharmaceutical drugs for obesity is a step toward health equity.⁶³ What is not promoted is that this message directly impacts Defendant’s pocketbooks by encouraging insurance to cover their drugs. Defendant’s messaging encourages patients and prescribers to forgo lifestyle changes – long the cornerstone of healthy weight loss – in favor of powerful, dangerous, and expensive drugs.

89. Anticipating the passage of this bill within the next few years, Morgan Stanley has forecast that U.S. revenue from such drugs will increase four-hundredfold by the end of the decade. Obesity looks “set to become the next blockbuster pharma category,” it declared, in a report last

⁵⁹ <https://www.essence.com/health-and-wellness/yvette-nicole-brown-fighting-obesity/> (last visited on September 18, 2023).

⁶⁰ <https://www.npr.org/sections/health-shots/2023/08/07/1192279278/ozempic-and-wegovy-maker-courts-prominent-black-leaders-to-get-medicare-favor> (last visited September 17, 2023)

⁶¹ <https://www.npr.org/sections/health-shots/2023/08/07/1192279278/ozempic-and-wegovy-maker-courts-prominent-black-leaders-to-get-medicare-favor> (last visited September 17, 2023)

⁶² <https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin> (last visited September 17, 2023); <https://www.fiercepharma.com/pharma/novo-nordisk-eli-lilly-and-boehringer-get-behind-lawmakers-bill-enable-obesity-drug-coverage> (accessed September 17, 2023)

⁶³ <https://www.statnews.com/2022/01/06/recognizing-obesity-as-a-disease-is-a-step-toward-health-equity/> (last visited on September 18, 2023); <https://www.womenshealthmag.com/health/a42679413/causes-of-obesity-genetics-lifestyle/> (last visited on September 18, 2023)

year, which also predicted that social media and word of mouth will create an “exponential virtuous cycle” around the new medications: a quarter of people with obesity will seek treatment from physicians, up from the current seven per cent, and more than half of those who do will begin taking medicine.⁶⁴

90. Defendants also own and operate several marketing campaign websites that are created for the purposes of educating on the science of obesity and creating a change in how obesity is understood and treated.

91. This includes the website “The Truth about Weight.”⁶⁵

92. This website includes headings such as “my weight, my culture” and these hashtags on Instagram appear to target Black, Brown, and Hispanic individuals.⁶⁶ The actor portrayed on this website are Black and Brown individuals.⁶⁷

93. Defendants also own and operate the website “It’s Bigger Than Me.”⁶⁸ This advertising campaign website promotes the message that obesity is a chronic health condition that requires pharmaceutical drugs to manage.⁶⁹

94. The hashtag #itsbiggerthan also reveals paid social media influencers promoting “body positivity” and linking back to Novo Nordisk’s website (and ultimately to their weight loss drugs).

95. Novo Nordisk’s presentation on capital markets day makes it clear that these campaigns are designed to “activate more people to seek treatment for obesity.”⁷⁰

⁶⁴ <https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin> (last visited on September 18, 2023).

⁶⁵ <https://www.truthaboutweight.com/> (last visited on September 18, 2023).

⁶⁶ <https://www.truthaboutweight.com/understanding-excess-weight/my-weight-my-culture.html> (last visited on September 18, 2023).

⁶⁷ *Id.*

⁶⁸ <https://www.itsbiggerthan.com> (last accessed September 18, 2023).

⁶⁹ *Id.*

⁷⁰ <https://www.novonordisk.com/content/dam/nncorp/global/en/investors/pdfs/capital-markets-day-2022/P5-obesity->

96. Defendants have also spent significant resources aligning themselves and infiltrating their influence into physician and advocacy groups.

97. This includes the American Board of Obesity Medicine. The former Director of the American Board of Obesity Medicine – who served from 2017 to November of 2021 – received payments by Novo Nordisk during her time as director of the American Board of Obesity Medicine.⁷¹

98. This former director of the American Board of Obesity Medicine currently promotes their GLP-1s for weight loss as part of their telehealth company and continues to receive payments.⁷²

99. At least one member of the American Board of Obesity Medicine that helped write the guidelines for obesity management has received payments directly from Novo Nordisk according to Open Payments Data during the same time he wrote the guidelines.⁷³

100. Novo Nordisk has also influenced and infiltrated the public health partners of the American Board of Obesity Medicine.

101. The American Board of Obesity Medicine lists public health “partners” on their website.⁷⁴

102. Novo Nordisk serves on the board or provides direct financial contributions to many of these public health advocacy groups.

care.pdf (last visited on September 18, 2023).

⁷¹ <https://joinfound.com/pages/medication-biology> (last visited on September 18, 2023); <https://openpaymentsdata.cms.gov/physician/1294300> (last visited on September 18, 2023); <https://www.linkedin.com/in/rekha-kumar-m-d-m-s-70b481237/> (last visited on September 18, 2023).

⁷² <https://joinfound.com/pages/medication-biology> (last visited on September 18, 2023); <https://openpaymentsdata.cms.gov/physician/1294300> (last visited on September 18, 2023); <https://www.linkedin.com/in/rekha-kumar-m-d-m-s-70b481237/> (last visited on September 18, 2023).

⁷³ <https://openpaymentsdata.cms.gov/physician/1379381> (last visited September 18, 2023); see also <https://www.abom.org/karl-nadolsky/>.

⁷⁴ <https://www.abom.org/> (last visited on September 18, 2023).

103. This includes Obesity in Action Coalition, to which Novo Nordisk contributes more than \$500,000 annually.⁷⁵ Novo Nordisk has been a partner since 2013, before any of its drugs were approved for weight loss.

104. Novo Nordisk also serves on the Corporate Council of American Society for Metabolic and Bariatric Society, another public health partner of the American Board of Obesity Medicine.⁷⁶

105. The pattern continues. Novo Nordisk is also a corporate member and directly financially contributes to Stop Obesity Alliance, yet another public health partner of the American Board of Obesity Medicine.⁷⁷

106. Novo Nordisk is a member of additional advocacy organizations and lobbying groups separate and apart from these public health partners of the American Board of Obesity Medicine.

107. This includes the Obesity Care Advocacy Network, which lobbies for legislation to expand access to Novo Nordisk's drugs.⁷⁸

108. In addition to promoting lobbying groups, Novo Nordisk has "paid more than \$250,000 in campaign contributions to members of Congress in an effort to pass legislation to make the U.S. government pay for Wegovy, a \$1,300-per-month-per-person proposition."⁷⁹

109. Novo Nordisk has also partnered with think tanks to promote their narrative that obesity is disease for which treatment requires their billion-dollar pharmaceutical drugs.

110. For example, the Milken Institute is a think tank focused on accelerating

⁷⁵ <https://www.obesityaction.org/corporate-partners/> (last accessed September 18, 2023).

⁷⁶ <https://asmbs.org/corporate-council> (last visited September 18, 2023).

⁷⁷ <https://stop.publichealth.gwu.edu/membership> (last visited on September 18, 2023).

⁷⁸ https://assets.obesitycareadvocacynetwork.com/TROA_fact_sheet_11_12_21_48098432e0/TROA_fact_sheet_11_12_21_48098432e0.pdf (last visited on September 18, 2023).

⁷⁹ <https://www.fiercepharma.com/marketing/health-group-lambasts-novo-nordisk-60-minutes-paid-news-program-weight-loss-med-wegovy> (last visited September 18, 2023).

measurable progress on the path to a meaningful life.⁸⁰

111. As early as 2019 – before Ozempic or Wegovy was approved for weight loss – Defendants were publishing articles on the Milken Institute about the “untold story of obesity.”⁸¹

112. Defendants have deceptively promoted their weight loss drugs on television and news segments.

113. For example, Novo Nordisk’s drugs were the subject of an investigative report on 60 Minutes that aired New Year’s Day of 2023.⁸²

114. Complaints have been filed alleging that the “news” piece was in reality “deceptive marketing” in which all physicians interviewed had received payments by Novo Nordisk.⁸³

115. The financial relationship between the physicians speaking about Wegovy and Ozempic and Novo Nordisk was not financial relationship was not explicitly disclosed on.⁸⁴ (The reporter, stated that the physicians had *advised* Novo Nordisk, but failing to state they had been compensated by the company.)⁸⁵

116. The nonprofit public health advocacy group the Physicians Committee issued a formal complaint that a recent CBS “60 Minutes” segment was a promotion for Novo Nordisk’s obesity drug, Wegovy, that was dressed up as a news segment.⁸⁶

117. The Washington, D.C.-based group has filed a complaint with federal bodies alleging that the CBS “60 Minutes” segment that aired on New Year’s Day breached the FDA’s

⁸⁰ <https://milkeninstitute.org/about> (last visited on September 18, 2023).

⁸¹ <https://milkeninstitute.org/article/untold-story-obesity-collaborating-across-sectors-make-care-happen> (last visited on September 18, 2023).

⁸² <https://www.cbsnews.com/news/wegozy-ozempic-explainer-60-minutes-2023-01-01/> (last visited September 18, 2023).

⁸³ <https://www.fiercepharma.com/marketing/health-group-lambasts-novo-nordisk-60-minutes-paid-news-program-weight-loss-med-wegovy> (last visited September 18, 2023).

⁸⁴ <https://fair.org/home/60-minutes-weight-loss-tip-dont-bite-the-hand-that-feeds-you/> (last visited on September 18, 2023).

⁸⁵ *Id.*

⁸⁶ *Id.*

“fair balance” rules for drug ads.⁸⁷

118. The Physician’s Committee said in a release that the feature failed to talk about alternatives to the drug or about other weight-loss methods; that only experts “paid by Novo” were used in the program; and that the piece used overly promotional language.⁸⁸

119. The FDA is currently investigating the marketing practices of Novo Nordisk.⁸⁹

120. In addition, upon information and belief, the FDA has issued a Form 483 that a site inspection of the Clayton, NC facility revealed “objectionable” conditions.⁹⁰

121. Novo Nordisk has spent millions of dollars delivering their message to physicians, healthcare providers, and consumers.

122. For example, Novo Nordisk spent over \$33,000,000 in 2022 on traditional physician marketing and detailing according to Open Payments Data.⁹¹

123. Defendants have directly and indirectly partnered with telehealth providers to promote their weight loss drugs.

124. This includes a 2019 **direct** partnership between Novo Nordisk and Noom, a leading behavior weight loss company.⁹²

125. After Saxenda was approved for weight loss, Noom joined with Novo Nordisk again to develop custom programs to accompany this weight loss medication.⁹³

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ <https://www.pcrm.org/news/news-releases/fda-confirms-investigation-novo-nordisk-ad-posed-60-minutes-story-about-weight> (last visited September 18, 2023)

⁹⁰ [https://www.investors.com/news/technology/novo-nordisk-stock-skids-as-report-finds-objectionable-conditions-at-wegovy-plant/#:~:text=Novo%20Nordisk%20\(NVO\)%20stock%20skidded,diabetes%20and%20weight%2Dloss%20drugs.](https://www.investors.com/news/technology/novo-nordisk-stock-skids-as-report-finds-objectionable-conditions-at-wegovy-plant/#:~:text=Novo%20Nordisk%20(NVO)%20stock%20skidded,diabetes%20and%20weight%2Dloss%20drugs.) (last visited September 18, 2023).

⁹¹ <https://openpaymentsdata.cms.gov/company/100000000144> (last visited September 18, 2023)

⁹² <https://www.prnewswire.com/in/news-releases/novo-nordisk-and-noom-to-partner-around-digital-health-solutions-to-help-people-with-obesity-lose-weight-and-keep-it-off-811725389.html> (last visited on September 18, 2023).

⁹³ <https://www.noom.com/blog/in-the-news/noom-announces-two-new-studies-on-impact-of-mobile-coaching-on-binge-eating-disorder-and-obesity/> (last visited on September 18, 2023).

126. Noom Med now provides to consumers – using physicians hired by Noom - prescriptions for weight loss directly to patients.⁹⁴

127. Noom Med promotes off label usage of these weight loss drugs on its website.⁹⁵

128. Noom currently has over 45 million users.⁹⁶

129. Other telehealth providers have jumped on board the band wagon in offering prescriptions directly to consumers for Defendants' weight-loss medications.

130. This includes Weight Watchers, who purchased telehealth startup Sequence for \$132,000,000 in order to provide weight loss medications to its subscribers.⁹⁷

131. There are currently over 3.5 million Weight Watchers subscribers.⁹⁸

132. It also includes Calibrate, yet another telehealth provider for weight loss medications, which raised \$100 million in capital funding from investors in 2021.

133. Calibrates' clinical advisory board includes Dr. Fatima Cody Stanford.⁹⁹

134. Dr. Cody Stanford is an obesity specialist that frequently speaks on behalf of Novo Nordisk, is featured on Novo Nordisk's website, and has received payments directly from Novo Nordisk.¹⁰⁰ Upon information and belief, Dr. Cody Stanford is one of the highest paid key opinion leaders for Novo Nordisk.

135. This financial and professional conflict of interest is not disclosed on Calibrate's

⁹⁴ <https://abcnews.go.com/GMA/Wellness/noom-joins-weight-watchers-offering-medications-wegovy-weight/story?id=99841160> (last visited on September 18, 2023).

⁹⁵ <https://www.noom.com/med/> (last visited on September 18, 2023).

⁹⁶ <https://exitsandoutcomes.com/free-excerpt-from-the-noom-report-a-45-million-moat/> (last visited September 18, 2023).

⁹⁷ <https://www.usatoday.com/story/news/health/2023/03/07/weightwatchers-sequence-wegovy-obesity-weight-loss-drugs/11415201002/> (last visited on September 18, 2023).

⁹⁸ <https://finance.yahoo.com/news/ww-international-inc-announces-first-200100340.html#:~:text=%E2%80%9CWe%20expect%20to%20end%202023,including%203.5%20million%20WeightWatchers%20subscribers> (last visited on September 18, 2023).

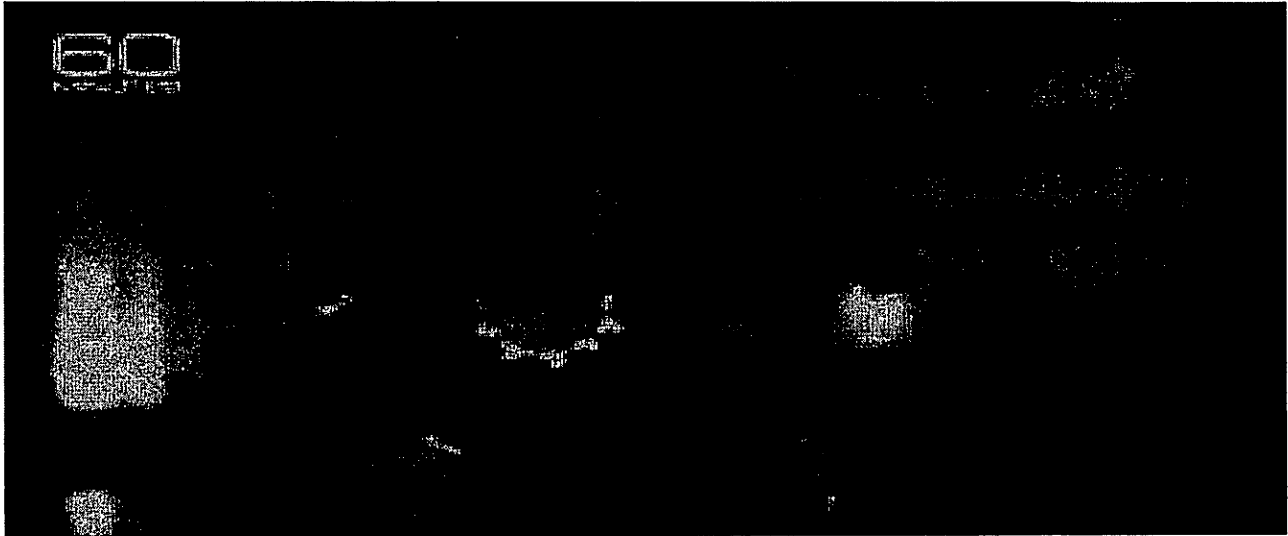
⁹⁹ <https://www.joincalibrate.com/about-us> (last visited on September 18, 2023).

¹⁰⁰ <https://openpaymentsdata.cms.gov/physician/807348> (last visited on September 18, 2023); <https://www.novonordisk-us.com/about/perspectives/changing-the-mindset-around-obesity.html> (last visited on September 18, 2023).

website.

136. This same clinical advisory board member, speaker, and promoter of Novo Nordisk is one of the doctors who appeared on the controversial 60 minutes news segment discussed above.

101



News reports have recognized that such marketing – particularly with telehealth providers - is a “gray area.”¹⁰²

137. Dr. Fatima Cody Stanford is also included on Novo Nordisk’s website, arguing that access to their weight loss drugs is an issue of equity and disparity for communities of color.¹⁰³

138. Their full financial relationship is not disclosed on the Defendants’ website.

139. Nor has Dr. Stanford disclosed this relationship in other seemingly independent publications arguing that obesity is a chronic disease that necessitates weight loss medications.¹⁰⁴

¹⁰¹ <https://mronline.org/2023/02/13/60-minutes-weight-loss-tip/> (last visited on September 18, 2023).

¹⁰² https://www.statnews.com/2023/04/06/weight-loss-drugs-wegovy-ro-telehealth-ozempic/?utm_campaign=morning_rounds&utm_medium=email&hsmi=253265291&hsenc=p2ANqtz-6H01FfkCg2JOnqJnju52tvRIJrTnn-KTwSkzAv1qkbBHi4MR2mN8wdPsbzj6Csbzm5s5M56muD-1rjaA-IF60zzjN1A&utm_content=253265291&utm_source=hs_email (last visited on September 18, 2023).

¹⁰³ <https://www.novonordisk-us.com/about/perspectives/changing-the-mindset-around-obesity.html> (last visited on September 18, 2023).

¹⁰⁴ <https://www.statnews.com/2022/01/06/recognizing-obesity-as-a-disease-is-a-step-toward-health-equity/> (last visited on September 18, 2023).

140. Collectively, the telehealth providers that Novo Nordisk directly and indirectly partners with and/or promotes account for approximately half of all weight loss prescriptions in 2022.¹⁰⁵

141. In sum, the Novo Nordisk Defendants promoted the safety, efficacy, and sale of Ozempic and Wegovy in the United States on its websites, in press releases, through in-person presentations, through the drug's label, in print materials, on social media, advocacy groups, lobbying groups, celebrity partnerships, telehealth partnerships, key opinion leaders, and through other public outlets.

142. Novo Nordisk's comprehensive, immersive marketing has left no stone unturned in delivering their message: Their drugs are the only safe and effective way to cure obesity long term.

III. Marketing Works: Novo Nordisk's Rampant Promotion Result in Thousands of Prescriptions and Billions in Sales

143. As a result of the Novo Nordisk Defendants' all-encompassing advertising and promotion efforts, Ozempic and Wegovy are widely prescribed throughout the United States.

144. As of August 10, 2023, Novo Nordisk reported that in the first six months of 2023 sales of Wegovy soared 344% in the U.S. alone to nearly \$1.7 billion, while sales of Ozempic jumped 50% to more than \$3.7 billion.¹⁰⁶

145. In July of 2021, doctors in the US wrote 94,000 prescriptions a week for Wegovy and 62,000 a week for Ozempic.¹⁰⁷

¹⁰⁵ <https://www.statnews.com/2023/08/10/wegovy-ozempic-weight-loss-telehealth-prescriptions/>

¹⁰⁶ <https://www.cnbc.com/2023/09/09/big-pharma-blockbuster-obesity-drug-battle-is-headed-for-100-billion.html#:~:text=Novo%20traded%20earnings%20jabs%20with,to%20more%20than%20%243.7%20billion.> (last visited September 18, 2023).

¹⁰⁷ <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html> (last visited on September 18, 2023).

146. It has been reported that the huge demand created by extensive marketing has lead to rampant off label usage and “gaming” the system to allow for insurance coverage.¹⁰⁸

147. On a year-end earnings call in 2022, Novo Nordisk cited worldwide market growth of fifty per cent, with almost **forty thousand new** Wegovy prescriptions being written every week.¹⁰⁹

148. The number of prescriptions filled reached an all-time high of 373,000 in one week in February of 2023, with more than half of those being new prescriptions.¹¹⁰

149. In June 2023, it was reported that new prescriptions for Ozempic had surged by 140 percent from the prior year.¹¹¹

150. It has reshaped Denmark’s economy as the country has reaped huge profits from the sale of the drug, which is now solely responsible for the country’s economic growth.¹¹²

151. Wegovy hit such a high demand that the company was not able to make enough, the company’s spokeswoman Ambre James- Brown said.¹¹³

152. There is now a shortage for the drugs, including those for people who have diagnosed Type II diabetes.¹¹⁴

¹⁰⁸ *Id.*

¹⁰⁹ <https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin> (last accessed September 18, 2023).

¹¹⁰ <https://www.cnn.com/2023/03/17/health/ozempic-shortage-tiktok-telehealth/> (last visited on September 18, 2023).

¹¹¹ <https://www.washingtonpost.com/business/2023/06/11/weight-loss-ozempic-wegovy-insurance/> (last visited on 8/1/23).

¹¹² https://www.nytimes.com/2023/08/28/business/denmark-ozempic-wegovy.html?action=click&pgtype=Article&state=default&module=style&weight-loss-drugs&variant=show®ion=MAIN_CONTENT_1&block=storyline_top_links_recirc (last visited on September 18, 2023).

¹¹³ <https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html> (last visited on September 18, 2023).

¹¹⁴ <https://www.forbes.com/sites/brianbushard/2023/09/16/shortage-of-weight-loss-drugs-like-wegovy-and-ozempic-persist-and-could-for-some-years/?sh=191877ce631e> (last visited September 17, 2023)

153. Ozempic and Wegovy have become so popular, Novo Nordisk has recently limited shipment to the US and paused advertising to address shortages.¹¹⁵

IV. Deceptive Marketing: Defendants Continuously Spread Misleading Marketing to Alter Perceptions of Ozempic and Wegovy's Safety Risks.

154. Despite Defendants focus on BMI and their marketing of Ozempic and Wegovy as health-promoting drugs, overall health is more than a simple number.

155. On June 14, 2023, adopted a new policy clarifying how body mass index should be used as a measure in medicine.¹¹⁶

156. The American Medical Association has urged doctors to deemphasize their use of body mass index (BMI) in determining healthy weights for patients.¹¹⁷

157. Due to significant limitations associated with the widespread use of BMI in clinical settings, the AMA suggests that it be used in conjunction with other valid measures of risk such as, but not limited to, measurements of visceral fat, body adiposity index, body composition, relative fat mass, waist circumference and genetic/metabolic factors.¹¹⁸

158. A recent study examined subjects' B.M.I.s in relation to their blood pressure, cholesterol levels, and insulin resistance. Nearly a third of people with a "normal" B.M.I. had unhealthy metabolic metrics, and nearly half of those who were technically overweight were metabolically healthy. About a quarter of those who were classified as obese were healthy, too.¹¹⁹

¹¹⁵ <https://www.theatlantic.com/health/archive/2023/05/ozempic-teen-obesity-treatment-health-promises-risks/674204/> (last visited on September 18, 2023).

¹¹⁶ <https://www.ama-assn.org/press-center/press-releases/ama-adopts-new-policy-clarifying-role-bmi-measure-medicine> (last visited September 18, 2023).

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ <https://www.newyorker.com/magazine/2023/03/27/will-the-ozempic-era-change-how-we-think-about-being-fat-and-being-thin> (last access September 18, 2023).

159. In short, BMI is a poor indicator of health outcomes for an individual.¹²⁰

160. Weight loss as the sole indicator of health has also been rejected by many clinicians in favor of improvements in other health outcomes and the assessing the whole health of an individual.¹²¹

161. These clinicians have cautioned that “a lower body weight does not always mean a person is healthier.”¹²²

162. It’s recognized in the medical community that weight loss achieved by Ozempic and Wegovy is often a result of a significant loss of muscle mass.¹²³

163. This loss of muscle mass can lead to sarcopenia – or “skinny fat” – in which the patient has decreased muscle mass, lessened bone density, and lower resting metabolic rate – all of which results in a loss of strength and functionality.¹²⁴

164. Ongoing use of Ozempic and Wegovy for weight loss can lead to malnutrition and key vitamin deficiencies, such a vitamin B12, that can lead to poor health outcomes.¹²⁵

165. Given these adverse effects on overall health, the National Institute of Care and Excellence (NICE) has recommended that people stop taking Wegovy after 2 years.¹²⁶

¹²⁰ <https://newsroom.uw.edu/resource/why-body-mass-index-doesnt-give-whole-health-picture> (last visited September 18, 2023).

¹²¹ <https://link.springer.com/content/pdf/10.1007/s11606-022-07821-w.pdf?pdf=button> (last visited on September 18, 2023); <https://newsroom.uw.edu/resource/why-body-mass-index-doesnt-give-whole-health-picture> (last accessed September 18, 2023).

¹²² <https://www.healthline.com/health-news/ozempic-muscle-mass-loss> (last accessed September 18, 2023).

¹²³ <https://www.nbcnews.com/health/health-news/weight-loss-drugs-muscle-loss-rcna84936> (last accessed September 18, 2023).

¹²⁴ <https://www.healthline.com/health-news/ozempic-muscle-mass-loss> (last accessed September 18, 2023).

¹²⁵ <https://www.nytimes.com/2023/04/21/well/eat/ozempic-side-effects-malnutrition.html> (last accessed September 18, 2023).

¹²⁶ National Institute for Health and Care Excellence. (2023). Semaglutide for managing overweight and obesity. *NICE*. Retrieved from: <https://www.nice.org.uk/guidance/ta875/chapter/1-Recommendations> (last visited on September 18, 2023).

166. The problem, of course, is that individuals immediately gain the weight back once they stop taking Ozempic and Wegovy.¹²⁷

167. Upon information and belief, the weight that is gained back is often visceral fat, which is considered more harmful to health than other types of fat.

168. Many clinicians recognize that a need to acknowledge that additional factors besides weight influence a person's health trajectory, including healthcare access, stress, poverty, and environmental threats (e.g., chemicals).¹²⁸

V. Defendants have long known that Ozempic and Wegovy are powerful, dangerous drugs.

169. As detailed below, the Defendants knew from its required premarket and post-market research and analytics that those drugs could cause malnutrition, cyclical vomiting, and gastroparesis, gastroenteritis, and intestinal obstruction/blockage.

170. The Novo Nordisk defendants have repeatedly failed to warn about the known dangerous side effects of Ozempic and Wegovy. This includes gastroparesis, gastroenteritis, intestinal blockage or obstruction, and malnutrition. All of these conditions can – and have – lead to hospitalization and/or death in patients across America.

171. Some doctors estimate that as many as 10% of patients discontinue use of these drugs due to the severity of side effects.¹²⁹

¹²⁷ <https://www.psychologytoday.com/ie/blog/the-neuroscience-of-eating-disorders/202303/ozempic-and-wegovy-is-semaglutide-a-miracle-weight> (last visited on September 18, 2023).

¹²⁸ *Id.*

¹²⁹ <https://www.cbsnews.com/news/ozempic-side-effects-weight-loss-drugs-wegovy-mounjaro-doctors-warn/> (last visited September 18, 2023)

172. Thousands have adverse event reports have been filed by the public with the FDA Adverse Event Reporting System. As of June 2022, the FDA had posted an alert that both Ozempic and Wegovy had potential safety signals for intestinal blockage.¹³⁰

173. As early as 2014, Defendants knew that Saxenda (liraglutide), Ozempic's predecessor, caused serious side effects and warned the end user of same.¹³¹

174. As early as 2019, Defendants knew that Rybelsus (Semaglutide), Ozempic's predecessor, caused serious side effects and warned the end user of same.

175. These side effects for Rybelsus included: nausea, abdominal pain, diarrhea, decreased appetite, vomiting, constipation, pancreatitis, diabetic retinopathy complication, hypoglycemia; acute kidney injury, and hypersensitivity reactions.¹³²

176. According to the FDA Adverse Event Reporting System, the Defendants were aware of reports of intestinal obstruction no later than 2019 for Ozempic and/or Wegovy.¹³³ These reports to the FDA also stated that many of these patients reporting intestinal obstruction or blockage were hospitalized.¹³⁴

177. The Prescribing Information for Ozempic discloses warnings, precautions, and adverse reactions associated with Ozempic but it does not disclose the risk of severe gastrointestinal events, including gastroparesis and gastroenteritis. Instead, it discloses delayed gastric emptying under the "Drug Interactions" heading and notes that Ozempic "may impact absorption of concomitantly administered oral medications." Further, under the "Mechanism of Action" section,

¹³⁰ <https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/april-june-2022-potential-signals-serious-risksnew-safety-information-identified-fda-adverse-event> (last visited September 18, 2023)

¹³¹ https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/206321orig1s0001bl.pdf (last visited on September 18, 2023).

¹³² <https://www.novo-pi.com/rybelsus.pdf> (last visited on September 18, 2023).

¹³³ <https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/8eef7d83-7945-4091-b349-e5c41ed49f99/state/analysis> (last access September 18, 2023).

¹³⁴ *Id.*

the Prescribing Information states that “[t]he mechanism of blood glucose lowering also involves a minor delay in gastric emptying in the early postprandial phase.”¹³⁵ These statements do not disclose gastroparesis or delayed gastric emptying as *risks* of taking Ozempic, nor do they disclose gastroparesis as a chronic condition that can result as a consequence of taking Ozempic.

178. The Prescribing Information for Wegovy discloses warnings, precautions, and adverse reactions associated with taking Wegovy but it does not disclose the risk of severe gastrointestinal events, including gastroparesis and gastroenteritis. Instead, it discloses delayed gastric emptying under the “Drug Interactions” heading and notes that Wegovy “may impact absorption of concomitantly administered oral medications.”¹³⁶ These statements do not disclose gastroparesis or delayed gastric emptying as *risks* of taking Wegovy, nor do they disclose gastroparesis as a chronic condition that can result because of taking Wegovy.

179. Defendants thus acknowledge that gastrointestinal events are well known side effects of the GLP-1 class.

180. Despite their experience and knowledge, Defendants have downplayed the severity of the gastrointestinal events caused by Ozempic, never, for example, warning of the risk of gastroparesis (“paralyzed stomach”), gastroenteritis, or intestinal blockage or obstruction.

181. Gastroparesis is a condition that affects normal muscle movement in the stomach. Ordinarily, strong muscular contractions propel food through the digestive tract. However, in a person suffering from gastroparesis, the stomach’s motility is slowed down or does not work at all, preventing the stomach from emptying properly. Gastroparesis can interfere with normal digestion, cause nausea, vomiting, abdominal pain, abdominal bloating, severe dehydration, a

¹³⁵ <https://www.novo-pi.com/ozempic.pdf> (last visited on September 18, 2023).

¹³⁶ https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215256s000lbl.pdf (last visited on September 18, 2023).

feeling of fullness after eating just a few bites, vomiting undigested food, undigested food that hardens and remains in the stomach, acid reflux, changes in blood sugar levels, lack of appetite, weight loss, malnutrition, and a decreased quality of life. There is no cure for gastroparesis.¹³⁷

182. Gastroenteritis refers to inflammation of the stomach and intestines. While viral gastroenteritis is also known as stomach flu, gastroenteritis may also be caused by ingesting medications.¹³⁸ Its symptoms include vomiting, nausea, diarrhea, stomach cramps, muscle aches, headaches, and fever.¹³⁹ Notably, vomiting and diarrhea can cause dehydration, which is the main complication of gastroenteritis, and which can lead to death.¹⁴⁰

183. Defendants do not disclose any risks associated with severe gastrointestinal events, including gastroparesis and gastroenteritis and intestinal blockage or obstruction, within the “Important Safety Information” section of their promotional website.

184. None of Defendants’ additional advertising or promotional materials warned prescription providers or the general public of the risk of severe gastrointestinal events, including gastroparesis, gastroenteritis, or intestinal blockage or obstruction.

185. A 2011 published article notes that “From extensive studies in experimental animals and humans we have found that GLP-1 also exerts a motility-inhibiting and antispasmodic

¹³⁷ <https://www.mayoclinic.org/diseases-conditions/gastroparesis/symptoms-causes/syc-20355787> (last visited on September 18, 2023).

¹³⁸ <https://www.merckmanuals.com/home/digestive-disorders/gastroenteritis/drug-related-gastroenteritis-and-chemical-related-gastroenteritis> (last visited on September 18, 2023).

¹³⁹ <https://www.mayoclinic.org/diseases-conditions/viral-gastroenteritis/symptoms-causes/syc-20378847> (last visited on September 18, 2023)

¹⁴⁰ <https://www.mayoclinic.org/diseases-conditions/viral-gastroenteritis/symptoms-causes/syc-20378847> (last visited on September 18, 2023).

effect in the gut that was verified in healthy volunteers...”.¹⁴¹ It is explicitly noted that GLP-1s have slow down gastric emptying.¹⁴²

186. A similar published article in 2013 found that after a review of PubMed articles it was evident that GLP-1s inhibit gastric emptying; notably, they separately found that delayed gastric emptying could lead to malnutrition.¹⁴³

187. A 2018 Case report found that Liraglutide had caused acute gastroparesis, and noted that “This case highlights the importance of considering drug-induced gastroparesis as an etiology of unexplained upper abdominal pain, nausea, and early satiety, especially in the absence of mechanical obstruction.”¹⁴⁴

188. In August of 2020, medical literature advised that some “patients do not know they have diabetic gastroparesis until they are put on a glucagon-like peptide 1 (GLP-1) receptor agonist such as ... semaglutide ... to manage their blood glucose.” The article went on to explain that “[t]his class of Ozempic can exacerbate the symptoms of diabetic gastroparesis. ... Thus, GLP-1 receptor agonist therapy is not recommended for people who experience symptoms of gastroparesis.”¹⁴⁵

189. In 2021, a case report was published regarding a 52-year-old female who had been taking weekly semaglutide injections approximately one month prior to the onset of gastroparesis

¹⁴¹ Hellström PM. GLP-1 playing the role of a gut regulatory compound. *Acta Physiol (Oxf)*. 2011 Jan;201(1):151-6. doi: 10.1111/j.1748-1716.2010.02150.x. PMID: 20518750; available at <https://pubmed.ncbi.nlm.nih.gov/20518750/> (last visited September 18, 2023).

¹⁴² *Id.*

¹⁴³ Luttikhoud J, de Ruijter FM, van Norren K, Diamant M, Witkamp RF, van Leeuwen PA, Vermeulen MA. Review article: the role of gastrointestinal hormones in the treatment of delayed gastric emptying in critically ill patients. *Aliment Pharmacol Ther*. 2013 Sep;38(6):573-83. doi: 10.1111/apt.12421. Epub 2013 Jul 23. PMID: 23879699. (last visited September 18, 2023).

¹⁴⁴ Rai P, Madi MY, Dickstein A. Liraglutide-induced Acute Gastroparesis. *Cureus*. 2018 Dec 28;10(12):e3791. doi: 10.7759/cureus.3791. PMID: 30868005; PMCID: PMC6402745; available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6402745/pdf/cureus-0010-00000003791.pdf> (last visited September 18, 2023).

¹⁴⁵ Young CF, Moussa M, Shubrook JH, *Diabetic Gastroparesis: A Review*, *Diabetes Spectr*. 2020 Aug; 33(3): 290–297, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7428659/> (last visited on September 18, 2023).

symptoms. The case report authors concluded that “thorough history taking revealed the cause [of gastroparesis] to be medication induced.”¹⁴⁶

190. A second case report also published in 2021 involved a 57-year-old female who had been taking weekly dulaglutide injections (another GLP-1 receptor agonist) for 15 months and suffering from bloating, nausea and vomiting for 12 of those months. Testing revealed delayed gastric emptying which improved with cessation of dulaglutide.¹⁴⁷

191. In 2022 a large, population-based study indicated that the use of GLP-1 RAs was associated with an increased risk of intestinal obstruction.¹⁴⁸

192. On June 29, 2023, the American Society of Anesthesiologists issued a warning that patients taking Ozempic should stop the medication at least a week before elective surgery because Ozempic and other GLP-1 agonists “delay gastric (stomach) emptying” and “the delay in stomach emptying could be associated with an increased risk of regurgitation and aspiration of food into the airways and lungs during general anesthesia and deep sedation.”¹⁴⁹

193. On July 25, 2023, it was reported that patients taking Ozempic had been diagnosed “with severe gastroparesis, or stomach paralysis, which their doctors think may have resulted from or been exacerbated by the medication they were taking, Ozempic.” Additionally, “[t]he US Food and

¹⁴⁶ Kalas MA, Galura GM, McCallum RW, *Medication-Induced Gastroparesis: A Case Report*, J Investig Med High Impact Case Rep. 2021 Jan-Dec; 9: 23247096211051919, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/> (last visited on September 18, 2023).

¹⁴⁷ Kalas MA, Galura GM, McCallum RW, *Medication-Induced Gastroparesis: A Case Report*, J Investig Med High Impact Case Rep. 2021 Jan-Dec; 9: 23247096211051919, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/> (last visited on September 18, 2023).

¹⁴⁸ Faillie, J.-L., Yin, H., Yu, O.H.Y., Herrero, A., Altwegg, R., Renoux, C. and Azoulay, L. (2022), Incretin-Based Drugs and Risk of Intestinal Obstruction Among Patients With Type 2 Diabetes. Clin. Pharmacol. Ther., 111: 272-282. <https://doi.org/10.1002/cpt.2430> (last visited September 18, 2023).

¹⁴⁹ <https://www.asahq.org/about-as/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should-stop-before-elective-surgery> (last visited on September 18, 2023).

Drug Administration said it has received reports of people on the Ozempic experiencing stomach paralysis[.]”¹⁵⁰

194. Case reports continue to be published regarding the use of semaglutide and intraoperative pulmonary aspirations.¹⁵¹

195. From the date the Novo Nordisk Defendants received FDA approval to market Ozempic until the present time, the Novo Nordisk Defendants made, distributed, marketed, and/or sold Ozempic without adequate warning to Plaintiff’s prescribing physician(s) and/or Plaintiff that Ozempic was associated with and/or could cause severe gastrointestinal issues including gastroparesis, gastroenteritis, and intestinal blockage or obstruction.

196. Defendants knew of the association between the use of GLP-1 receptor agonists and the risk of developing severe gastrointestinal issues, including gastroparesis and gastroenteritis. Defendants’ knowledge derived from their clinical studies, case reports, and the medical literature, including the medical literature and case reports referenced above in this Complaint.

197. Upon information and belief, Defendants ignored the association between the use of GLP-1 receptor agonists and the risk of developing severe gastrointestinal issues, including gastroparesis and gastroenteritis.

198. Defendants’ failure to disclose information that they possessed regarding the association between the use of GLP-1 receptor agonists and the risk of developing severe gastrointestinal issues, including gastroparesis and gastroenteritis, rendered the warnings for this medication inadequate.

¹⁵⁰ <https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-Ozempic-gastroparesis/index.html> (last visited September 18, 2023).

¹⁵¹ <https://pubmed.ncbi.nlm.nih.gov/36977934/> (last visited September 18, 2023)

199. By reason of the foregoing acts and omissions, Plaintiff was and still is caused to suffer from severe gastrointestinal issues, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

VI. The Dark Side of Ozempic and Wegovy

200. It has been recognized in the media that in the aftermath of the marketing frenzy created by Novo Nordisk that the full risks of this drug are not understood or readily available to the average patient – and perhaps the average provider.¹⁵²

201. For example, one physician has stated that “I suspect the drug companies are downplaying this risk because women are probably the biggest part of the market share,” she said. “The world doesn’t value women, and this is seen in women’s health as well.”¹⁵³

202. Strikingly, Novo Nordisk’s own hired spokesperson and consultant has stated on national television that “Doctors do not understand obesity.”¹⁵⁴

203. It is unclear how Novo Nordisk would expect a doctor to understand the mechanism of their weight loss drug – and its corresponding risks – if they do not understand the condition it is supposed to treat.

204. The Defendant has much greater knowledge of their obesity drugs – including their dangerous risks – than the medical community or American public.

205. Recently, news articles have begun to publicize the dark side of these drugs.¹⁵⁵

¹⁵² <https://www.vox.com/science/23683383/ozempic-pregnancy-risks-side-effect-semaglutide-wegovy>

¹⁵³ <https://www.vox.com/science/23683383/ozempic-pregnancy-risks-side-effect-semaglutide-wegovy> (last visited September 18, 2023).

¹⁵⁴ <https://www.cbsnews.com/news/weight-loss-obesity-drug-2023-01-01/> (last visited September 18, 2023).

¹⁵⁵ <https://www.cnn.com/2023/06/07/opinions/ozempic-weight-loss-drug-diet-culture-wellness-carr-goldynia-sole-smith/index.html> (last visited September 18, 2023).

206. Consumers of Ozempic and Wegovy are reporting major health problems, including gastroparesis, stomach paralysis, gastroenteritis, and intestinal blockage or obstruction.¹⁵⁶

207. Consumers are not aware that taking Ozempic or Wegovy can lead to severe malnutrition.¹⁵⁷

208. Consumers are not aware that taking Ozempic and Wegovy can lead to severe muscle loss.¹⁵⁸

209. Muscle loss (sarcopenia) can lead to death.¹⁵⁹

210. Other industry experts, including physicians, believe that there needs to be greater awareness of the risks of Ozempic and Wegovy.¹⁶⁰

211. Yet Defendants have continued selling Ozempic and Wegovy to a point where there are mass shortages and waitlists.¹⁶¹

212. This is despite the fact the FDA has investigated and found “objectionable” conditions at Novo Nordisk’s Clayton, N.C. manufacturing plant that is responsible for making weight loss drugs like Ozempic and Wegovy.¹⁶²

¹⁵⁶ <https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/8cef7d83-7945-4091-b349-e5c41ed49f99/state/analysis> (last visited September 18, 2023).

¹⁵⁷ [An Extreme Risk of Taking Ozempic: Malnutrition – The New York Times \(nytimes.com\)](#) (last visited September 18, 2023).

¹⁵⁸ <https://www.healthline.com/health-news/ozempic-muscle-mass-loss> (last visited September 18, 2023).

¹⁵⁹ <https://my.clevelandclinic.org/health/diseases/23167-sarcopenia#:~:text=Sarcopenia%20affects%20your%20musculoskeletal%20system,risk%20of%20complications%20including%20death> (last visited on September 18, 2023).

¹⁶⁰ <https://www.vox.com/science/23683383/ozempic-pregnancy-risks-side-effect-semaglutide-wegovy> (last visited September 18, 2023).

¹⁶¹ https://www.nytimes.com/2023/08/28/business/denmark-ozempic-wegovy.html?action=click&pgtype=Article&state=default&module=style&n-weight-loss-drugs&variant=show®ion=MAIN_CONTENT_1&block=storyline_top_links_recirc (last visited September 18, 2023).

¹⁶² [https://www.investors.com/news/technology/novo-nordisk-stock-skids-as-report-finds-objectionable-conditions-at-wegovy-plant/#:~:text=Novo%20Nordisk%20\(NVO\)%20stock%20skidded,diabetes%20and%20weight%20loss%20drugs](https://www.investors.com/news/technology/novo-nordisk-stock-skids-as-report-finds-objectionable-conditions-at-wegovy-plant/#:~:text=Novo%20Nordisk%20(NVO)%20stock%20skidded,diabetes%20and%20weight%20loss%20drugs) (last visited September 18, 2023).

213. This is not the first time the FDA has cited a company for failures related to the manufacturing of Wegovy and Ozempic. In January 2021, a US FDA Form 483 revealed that Catalent failed to impellent sustainable corrective action and preventive action and had inadequate maintenance at a Catalent fill/finish facility.¹⁶³ Novo Nordisk confirmed that “a contract manufacturer doing syringe filling on the GLP-1 med had temporarily halted delivered following a good manufacturing practices glitch.”¹⁶⁴

214. Defendants are profiting while the end consumers – mostly women - are suffering.

PARTY PLAINTIFF

215. Plaintiff, Kelly Miller, was born on July 21, 1985, and is currently 38 years old.

216. In January of 2023, she went to Reading Hospital Weight Loss Surgery and Wellness Center and was seen by Dr. Jerome Lazor to discuss options available to her to lose weight.

217. Prior to seeking out weight loss assistance, Mrs. Miller had seen and heard marketing regarding Ozempic and Wegovy.

218. Mrs. Miller relied upon the information and images conveyed in this marketing when requesting weight loss medication.

219. Mrs. Miller was subsequently prescribed Wegovy in January of 2023.

220. Mrs. Miller began suffering from severe stomach cramping, vomiting, nausea, and fatigue in approximately July of 2023.

221. On July 30, 2023, Mrs. Miller’s symptoms escalated further, and she could not tolerate any oral intake of food or liquids.

¹⁶³ <https://bioprocessintl.com/bioprocess-insider/regulations/fda-483-shows-7-observations-at-catalent-fill-finish-plant-in-belgium/> (last visited September 18, 2023); <https://www.fiercepharma.com/manufacturing/inside-catalent-fda-citation-allegedly-at-heart-novo-nordisk-s-wegovy-supply-hiccup> (last visited September 18, 2023).

¹⁶⁴ *Id.*

222. On July 31, 2023, Mrs. Miller was hospitalized due to her worsening condition.

223. During her hospitalization she was given several tests and ultimately diagnosed with gastroparesis.

224. Mrs. Miller was ultimately released from the hospital on August 3, 2023.

225. Mrs. Miller discontinued use of Wegovy at the advice of her medical team.

226. Unfortunately, however, she continues to suffer from sequelae of gastroparesis, which negatively affects her daily life.

227. Mrs. Miller continues to receive treatment and follow-up appointments for her gastroparesis.

228. At all times material to the above, the Wegovy label failed to adequately warn Mrs. Miller of the potential risks of taking Wegovy.

229. At all times material to the above, the Wegovy marketing and advertising failed to adequately warn Mrs. Miller of the potential risk of taking Wegovy.

CAUSES OF ACTION

COUNT I: NEGLIGENCE

230. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

231. Plaintiff brings this claim against Defendants for defective design.

232. Defendants, directly or indirectly, caused Wegovy and/or Ozempic to be sold, distributed, packaged, labeled, marketed, promoted, and used by Plaintiff. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Wegovy and/or Ozempic within the Commonwealth of Pennsylvania and throughout the United States.

233. At all relevant times, Defendants had a duty to exercise reasonable care in the manufacture, marketing, advertisement, supply, storage, transport, packaging, sale, and distribution of Wegovy and/or Ozempic products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that did not cause users to suffer from unreasonable, dangerous side effects when used alone or in foreseeable combination with other drugs.

234. At all relevant times, Defendants knew, or in the exercise of reasonable care, should have known of the hazards and dangers associated with Wegovy and/or Ozempic, and specifically that use of these drugs could cause gastroparesis, gastroenteritis, malnutrition, intestinal obstruction, hospitalization, and death.

235. At all relevant times, Defendants knew, or in the exercise of reasonable care, should have known that the use of Wegovy and/or Ozempic could cause Plaintiff's injuries, and thus, created a dangerous and unreasonable risk of injury to the users of these products.

236. Defendants knew, or in the exercise of reasonable care, should have known that users and consumers were unaware of the risks and magnitude of the risks associated with the use of Wegovy and/or Ozempic.

237. Defendants breached their duty of care to the Plaintiff and her physician, in the testing, monitoring, and pharmacovigilance of Ozempic and Wegovy.

238. In disregard of their duties, Defendants committed one or more of the following negligent acts or omissions:

- a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and distributing Ozempic and Wegovy, without thorough and adequate pre- and post-market testing of the product;

- b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, and distributing Ozempic and Wegovy, and upon information and belief, while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Ozempic and Wegovy;
- c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Ozempic and Wegovy were safe for their intended use;
- d. Upon information and belief, failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendant knew and had reason to know that Ozempic/Wegovy was indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users;
- e. Failing to warn the Plaintiff, the medical and healthcare community, and consumers that Ozempic and Wegovy's risk of harm was unreasonable and that there were safer and effective alternative products available to Plaintiff and other consumers;
- f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would use Ozempic and Wegovy;
- g. Advertising, marketing, and recommending the use of Ozempic and Wegovy, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with, and inherent in, the use of Ozempic and Wegovy;
- h. Representing that Ozempic and Wegovy were safe for weight loss when in fact Defendants knew and/or should have known the products were not safe for those purposes;
- i. Continuing to manufacture and sell Ozempic and Wegovy with the knowledge that Ozempic and Wegovy, when used for weight loss, were unreasonably unsafe and dangerous;

- j. Failing to use reasonable and prudent care in the design, research, testing, manufacture, and development of Ozempic and Wegovy, so as to avoid the risk of serious harm associated with the use of Ozempic and Wegovy. Failing to design and manufacture Ozempic and Wegovy so as to ensure the drugs were at least as safe and effective as other similar products;
- k. Failing to ensure that Ozempic and Wegovy were accompanied by proper and accurate warnings about the risk of severe gastrointestinal problems including gastroparesis.
- l. Failing to ensure that Ozempic and Wegovy were accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Ozempic and Wegovy and that use of Ozempic and Wegovy created a high risk of severe injuries; and
- m. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Ozempic and Wegovy.

239. A reasonable manufacturer, designer, distributor, promotor, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

240. As a direct and proximate result of the Defendants' negligent testing, monitoring, and pharmacovigilance of Ozempic and Wegovy, Defendants introduced a drug into this Commonwealth that they knew or should have known would cause serious and severe gastrointestinal issues in people including gastroparesis, an incurable condition, and Plaintiff has been injured catastrophically and sustained severe and permanent pain, suffering, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

241. The aforementioned negligence and wrongs done by the Defendants were aggravated by the kind of grossly negligent conduct and disregard for the rights of others, the public, and Plaintiff, for which the law allows the imposition of exemplary or punitive damages,

in that Defendants' conduct involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants proceeded with a reckless disregard to the rights, safety, or welfare of others, including the Plaintiff.

242. Defendant is liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania law.

243. As a direct and proximate result of one or more of the above-stated negligent acts by Defendants, Plaintiff suffered bodily injuries and consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages.

WHEREFORE, Plaintiff requests judgment for compensatory and punitive damages against all Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT II: NEGLIGENCE (FAILURE TO WARN)

244. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

245. Ozempic and/or Wegovy are products within the meaning of Pennsylvania products liability law.

246. Ozempic and/or Wegovy was expected to reach, and did reach, users and/or consumers, including Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

247. Defendant owed Plaintiff and other Ozempic and/or Wegovy users a duty to exercise reasonable care in marketing, advertising, promoting, distributing and/or selling Ozempic and/or Wegovy.

248. Defendant advertised and promoted Ozempic and/or Wegovy for the purpose of weight loss and diabetes control.

249. At all times material, Ozempic and/or Wegovy was used in a manner intended and/or foreseeable to the Defendant.

250. A reasonable patient or consumer of Ozempic and/or Wegovy would expect the drug to be free of significant defects.

251. Defendant knew or had reason to know of facts establishing that Ozempic and/or Wegovy posed a significant risk of retinal or macular toxicity and deliberately proceeded to act, or failed to act, in conscience disregard of, or indifference, to that risk.

252. At all times relevant hereto, the defective nature of Ozempic and/or Wegovy was known to Defendant, or reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their respective products, and not known to ordinary physicians who would be expected to prescribe the drug to their patients.

253. In disregard of its duty to timely warn consumers of health risks associated with Ozempic and/or Wegovy, Defendant committed one or more of the following negligent acts or omissions:

- a. Failing to properly and adequately warn and instruct Plaintiff and Plaintiff's treating physicians that Wegovy and/or Ozempic was designed and/or manufactured in a way that it could cause injuries and damages, including lasting and permanent gastrointestinal injuries;
- b. Failing to timely disclose to Plaintiff and Plaintiff's treating physicians the risks of gastrointestinal injury, including gastroparesis and intestinal obstruction, associated with Ozempic and/or Wegovy in the product's labeling;

- c. Failing to timely warn Plaintiff and Plaintiff's treating physicians that a detailed lab work and patient history should be obtained before starting Ozempic and/or Wegovy;

254. The labels for Wegovy and/or Ozempic were inadequate because they did not warn and/or adequately warn of all possible adverse side effects associated with the use of Wegovy and/or Ozempic, including the increased risk of severe gastrointestinal events (e.g., gastroparesis, gastroenteritis, intestinal blockage, and malnutrition).

255. The labels for Wegovy and/or Ozempic were inadequate because they did not warn and/or adequately warn that Wegovy and/or Ozempic had not been sufficiently and/or adequately tested for safety risks, including severe gastrointestinal events (e.g., gastroparesis, gastroenteritis, intestinal blockage, and malnutrition).

256. The labels for Wegovy and/or Ozempic were inadequate because they did not warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of Wegovy and/or Ozempic.

257. The labels for Wegovy and/or Ozempic were inadequate because they did not warn and/or adequately warn of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects.

258. Communications made by Defendants to Plaintiff and her prescribing physician(s) were inadequate because Defendants failed to warn and/or adequately warn of all possible adverse side effects associated with the use of Wegovy and/or Ozempic, including the increased risk of severe gastrointestinal events (e.g., gastroparesis, gastroenteritis, intestinal blockage, and malnutrition).

259. Communications made by Defendants to Plaintiff and her prescribing physician(s) were inadequate because Defendants failed to warn and/or adequately warn that Wegovy and/or Ozempic had not been sufficiently and/or adequately tested for safety risks, including severe gastrointestinal events (e.g., gastroparesis and gastroenteritis, intestinal blockage, and malnutrition).

260. Defendant's failure to warn of the above was the proximate cause of Plaintiff's injuries, harm, and economic loss, from which Plaintiff continue to suffer.

261. Defendant's failure to warn of the significant risks of Wegovy and/or Ozempic use prevented Plaintiff and Plaintiff's treating physicians from conducting a proper assessment of the risks and benefits of using Wegovy and/or Ozempic.

262. Had Plaintiff and/or Plaintiff's treating physicians been properly warned of the significant risks of Wegovy and/or Ozempic, they would not have elected to begin and/or continue Wegovy and/or Ozempic therapy.

263. Defendants is liable in tort to Plaintiff for its wrongful conduct pursuant to Pennsylvania.

264. As a direct, foreseeable and proximate result of Defendant's failure to warn of the significant risks associated with Wegovy and/or Ozempic, Plaintiff suffered grievous bodily injuries and consequent economic and other losses, as referenced above. As a consequence of Defendant's misconduct, Plaintiff' physicians lacked adequate warnings and other appropriate facts that were misrepresented or omitted from the information (if any) that Defendant provided to physicians for Wegovy and/or Ozempic. Plaintiff suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income and disability, and punitive damages.

WHEREFORE, Plaintiff requests judgment for compensatory and punitive damages against all Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT III: NEGLIGENCE (DESIGN DEFECT)

265. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

266. 91. Defendant is liable to Plaintiff for the injuries and damages sustained due to Defendant's negligent design and/or formulation of Wegovy and/or Ozempic.

267. At all relevant times to this lawsuit, Defendant owed a duty to consumers including Plaintiff and their health care providers, to assess, manage, and communicate the risks, dangers, and adverse effects of Wegovy and/or Ozempic. The Defendant's duties included, but were not limited to, carefully and properly designing, testing, studying, and manufacturing Wegovy and/or Ozempic.

268. The Defendant negligently and carelessly breached the above-described duties to Plaintiff by, among other acts and omissions, negligently and carelessly:

(a) Failing to use ordinary care in designing, testing, and manufacturing Wegovy and/or Ozempic;

(b) Failing to design Wegovy and/or Ozempic as to properly minimize the adverse effects to the gastrointestinal and immune system;

(c) Failing to counteract in the design the known adverse effects on the gastrointestinal and immune system;

(d) Designing a product where the benefits were greatly outweighed by the risks gastroparesis, gastroenteritis, intestinal obstruction, malnutrition, hospitalization, and death;

(e) Designing a product without taking into consideration the proper dosage that could avoid or reduce damage to the retina.

269. Furthermore, Wegovy and/or Ozempic was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeded the benefits associated with the design or formulation.

270. At all reasonable times, given their lack of efficacy and increased safety risks, Wegovy and/or Ozempic did not meet the reasonable expectations of an ordinary consumer, particularly the Plaintiff.

271. Wegovy and/or Ozempic was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, it was unreasonably dangerous, more dangerous than an ordinary consumer would expect, and more dangerous than other similar drugs.

272. Despite Defendant's knowledge of the foreseeable risks and unreasonably dangerous nature of Wegovy and/or Ozempic at all times relevant, Defendant designed and brought the product to market and continued to market the drug when there were safer alternatives available, including but not limited to alternate dosing, reduced exposure, among others.

273. As a result of Defendants' negligent and reckless design, Plaintiff sustained severe and ongoing injuries.

274. Defendant is liable in tort to Plaintiff for its wrongful conduct pursuant to Pennsylvania and/or the law of their home state.

275. As a direct and proximate result of one or more of the above-stated negligent acts by Defendant, Plaintiff suffered grievous bodily injuries and consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages.

WHEREFORE, Plaintiff requests judgment for compensatory and punitive damages against all Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT IV: NEGLIGENT MISREPRESENTATION AND MARKETING

276. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

277. At all relevant times, Defendant negligently provided Plaintiff, their healthcare providers, and the general medical community with false or incorrect information or omitted or failed to disclose material information concerning Wegovy and/or Ozempic, including, but not limited to, misrepresentations and marketing regarding the safety and known risks of Wegovy and/or Ozempic.

278. The information distributed by the Defendant to the public, the medical community, Plaintiff and their healthcare providers, including advertising campaigns, labeling

materials, print advertisements, commercial media, and marketing was false and misleading and contained omissions and concealment of truth about the dangers of Wegovy and/or Ozempic.

279. Defendant's conduct had the capacity to deceive and/or purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff and Plaintiff's health care providers; to falsely assure them of the quality of Wegovy and/or Ozempic. and induce the public and medical community, including Plaintiff and their healthcare provider to request, recommend, purchase, and prescribe Wegovy and/or Ozempic.

280. Defendant had a duty to accurately and truthfully represent and market to the medical and healthcare community, medical pharmaceutical manufacturers, Plaintiff, their healthcare providers and the public, the known risks of Wegovy and/or Ozempic, including its propensity to cause gastroparesis, gastroenteritis, intestinal blockage/obstruction, and malnutrition.

281. Defendant made continued omissions in the Wegovy and/or Ozempic labeling, including promoting it as safe and effective while failing to warn of its propensity to cause to cause gastroparesis, gastroenteritis, intestinal blockage/obstruction, and malnutrition.

282. Defendant made additional misrepresentations beyond the product labeling by representing Wegovy and/or Ozempic as a safe and effective treatment for diabetes and weight-loss with only minimal risks.

283. Defendant misrepresented and overstated the benefits of Wegovy and/or Ozempic to Plaintiff, Plaintiff's treaters, and the medical community without properly advising of the known risks to patients.

284. Defendants made the misrepresentations alleged herein with the intent to induce consumers, like Plaintiff, to take their weight loss products.

285. In reliance upon the false, deceptive and negligent misrepresentations and omissions and marketing made by the Defendant, Plaintiff and Plaintiff's healthcare providers were induced to, and did use and prescribe Wegovy, and relied upon the affirmative misrepresentations and/or negligent omissions in doing so.

286. As a direct and proximate result of the foregoing negligent misrepresentations and marketing and conduct with capacity to deceive and/or intention to deceive, Plaintiff suffered serious and ongoing injuries.

287. As a direct and proximate result of the foregoing misrepresentations, marketing, and deceitful intentions, Plaintiff requires and/or will require more healthcare and services and did incur medical, health, incidental, and related expenses.

288. Defendant knew or should have known that the Plaintiff, Plaintiff's healthcare providers, and the general medical community did not have the ability to determine the true material facts which were intentionally and/or negligently concealed and misrepresented by the Defendant.

289. Plaintiff and their healthcare providers would not have used or prescribed Wegovy and/or Ozempic had the true facts not been concealed by the Defendant.

290. Defendant had sole access to many of the material facts concerning the defective nature of Wegovy and/or Ozempic and its propensity to cause serious and dangerous side effects.

291. At the time Plaintiff were prescribed and administered Wegovy and/or Ozempic, Plaintiff and their healthcare providers were unaware of Defendant's negligent misrepresentations and omissions.

292. The Defendant failed to exercise ordinary care in making representations concerning Wegovy and/or Ozempic while they were involved in their manufacture, design, sale, testing, quality assurance, quality control, promotion, marketing, labeling, and distribution in interstate commerce, because the Defendant negligently misrepresented Wegovy and/or Ozempic's high risk of unreasonable and dangerous adverse side effects.

293. Plaintiff and Plaintiff's healthcare providers reasonably relied upon the misrepresentations and omissions made by the Defendant, where the concealed and misrepresented facts were critical to understanding the true and full dangers inherent in the use of the Wegovy and/or Ozempic.

294. Plaintiff and Plaintiff' healthcare providers' reliance on the foregoing misrepresentations and omissions was the direct and proximate cause of Plaintiff' injuries.

WHEREFORE, Plaintiff requests judgment for compensatory and punitive damages against all Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

COUNT V: VIOLATION OF PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW 73 P.S. SECT. 201-1

295. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

296. Defendants financed, assisted, supported and participated in the promotion and use of Wegovy and/or Ozempic in order to create a demand for the drug.

297. Defendants deliberately and/or negligently misrepresented the safety of Wegovy and/or Ozempic and concealed the risks attendant to use of the drug. Through their misrepresentations, Defendants' conduct had the tendency or capacity to deceive, and affected the decisions of consumer and their health care providers to purchase, prescribe and use Wegovy and/or Ozempic, and to exclude the options of not using a drug product for treatment.

298. All Defendants, while engaged in the conduct and practices identified above, committed one or more violations of state laws related to unfair or deceptive acts or practices, including, but not limited to, the following:

- a. Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of Wegovy and/or Ozempic;
- b. Representing that Wegovy and/or Ozempic have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have;
- c. Representing that Defendant authors, key opinion leaders, consultants, and speakers do not have a sponsorship, approval, status, affiliation or connection that they do have;

- d. Representing that Wegovy and/or Ozempic are of a particular standard, quality or grade;
- e. Engaging in other fraudulent or deceptive conduct which creates likelihood of confusion or of misunderstanding, as alleged in this Complaint.

299. Plaintiff have suffered injuries and damages as a direct and proximate result of Defendants' statements in the advertising and promotional activities to Plaintiff and their medical providers, as described above.

WHEREFORE, Plaintiff requests judgment for actual and treble damages against all Defendants, jointly and severally, reasonable attorney fees, costs of this suit, and interest at the legal rate.

DEMAND FOR JURY TRIAL

300. Plaintiff demands a trial by jury on all the triable issues within this pleading.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein, and prays for judgment in her favor and against the Defendants awarding the following:

301. A monetary award, sufficient to compensate Plaintiff for the following categories of damages:

- a. actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;
- b. actual and treble damages in such amount to be determined by this Court and as provided by law;
- c. exemplary and punitive damages sufficient to punish and deter the Defendants and others from future wrongful practices;
- d. pre-judgment and post-judgment interest;
- e. costs including court costs, and other litigation expenses; and

f. any other relief the Court may deem just and proper.

Dated: September 19, 2023

Respectfully Submitted,

/s/ Esther Berezofsky

Esther Berezofsky, Esq.

Attorney I.D. No. 50151

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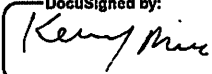
Fax: (401) 457-7708

Counsel for Plaintiff

VERIFICATION

I, Kelly A Miller, hereby state:

1. I am the plaintiff in this action;
2. I verify that the statements made in the foregoing Complaint are true and correct to the best of my knowledge, information and belief; and
3. I understand that the statements in the Complaint are made subject to the penalties of 18 Pa.C.S. § 4904 relating to unsworn falsification to authorities.

DocuSigned by:

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Plaintiff

09/18/2023

Date